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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,296	12/04/2000	Christopher M. Sidebottom	PM 270652	1658

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EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1653	18

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/582,296	Applicant(s) SIDEBOTTOM ET AL.
	Examiner Roy Teller	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *7-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-9* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to a product, anti-freeze protein, are for example classified in Class 530, subclass 350.

II. Claim 7, drawn to a nucleic acid of the anti-freeze protein, classified in Class 536, subclass 22.1.

III. Claims 8-9, drawn to a process of use, a food product, are for example classified in Class 426.

The inventions are distinct, each from the other for the following reasons:

Inventions of group I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the food product can be used as food as opposed to a protein that improves the freezing tolerance of foodstuffs.

The nucleic acid of group II is related to the anti-freeze protein of group I by virtue of encoding the same. Although the nucleic acid and protein are related because the nucleic acid sequence is specific for the claimed protein, they are distinct inventions because they are

physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as synthetic peptide synthesis or purification from a natural source.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37CFR 1.143).

A telephone call was made to Paul Kokulis on 5/21/02, resulting in an oral election of group I, claims 1-6, with group III, claims 8-9, being traversed .

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

Claims 1 –6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for anti-freeze protein does not reasonably provide enablement for modified versions and isoforms of the protein.The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use modified versions or isoforms of the protein of the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;

2) the breadth of the claims;

3) the predictability or unpredictability of the art;

4) the amount of direction or guidance presented;

5) the presence or absence of working examples;

6) the quantity of experimentation necessary;

7) the state of the prior art; and,

8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

1) the nature of the invention;

Claim 1 and 2 are directed to "... modified versions and isoforms" of anti-freeze protein from lichen.

2) the breadth of the claims;

Claims 1 –6 do not define the metes and bounds of "... modified versions and isoforms of the protein." With regard to all single and/or multiple substitutions, insertions and deletions as well as any one or more single and multiple combinations thereof.

3) the predictability or unpredictability of the art;

Generally, function cannot be predicted based on structural information alone. In Carson (WO 94/14472) a sequence that is 51% identical to SEQ ID NO: 1 of applicant's is used as an anti-adhesion enzyme to treat an acute inflammatory condition. In Alkhatib (Virology, 1986, 150, pp. 479-490) a sequence that is 42% identical to SEQ ID NO: 2 of applicant's is a structure of the measles virus hemagglutinin, whose function causes disease. Both of the examples cited fall within the claims "... modified versions and isoforms of the protein." Especially when the claims do not explicitly require by claim terminology that the "modified versions and isoforms" maintain the claim 1 at least 80% identity.

4) the amount of direction or guidance presented;

Specifications lacked direction or guidance in the results of "... modified versions and isoforms of the protein." Page 5, lines 5-6 of the specifications state "... scope of present invention are modified versions of the ... protein.", yet no guidance was provided in how to

make and/or use the modified versions of the protein. Examples 1-4 of the specification did not address modified versions and isoforms of the protein.

5) the presence or absence of working examples;

Specification lacked working examples for "...modified versions and isoforms of the protein." Examples 1-4 of the specification did not address how to make and/or use modified versions and isoforms of the protein nor appear to disclose what would or would not have been the modified forms and versions of the protein let alone define the part(s) of the protein conferring anti-freeze function.

6) the quantity of experimentation necessary;

Undue experimentation would be necessary to determine what the specific biological activities of the modified versions and isoforms of the protein would have been that, e.g., retained anti-freeze function.

7) the state of the prior art;

In Carson, (WO 94/14472) a sequence that is 51% identical to SEQ ID NO:1 of applicant's is used as an anti-adhesion enzyme to treat an acute inflammatory condition. In Alkhatib, (Virology, 1986, 150, pp 479-490) a sequence that is 42% identical to SEQ ID NO:2 of applicant's is a structure of the measles virus hemagglutinin, whose function causes disease. These divergent examples fall under the umbrella of "...modified versions and isoforms of the protein".

8) the relative skill of those skilled in the art;

The level of skill in this art is at least that of a PhD. with several years experience in the art.

In consideration of each of factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosures, examples, teaching, and guidance presented. Absent factual data to the contrary the amount and level of experimentation needed is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 contain the wording "... and modified versions and isoforms of this protein." The wording of claims 1 and 2 would require some functional limitations of the modified versions and isoforms, however, as currently presented are indefinite as to what the modifications are and what are the isoforms to which the claims refer and whether or not the isoforms and modified versions would have to have at least 80% identity.

Claim 1 refers to 80% identity to SEQ ID NO:1 but fails to define which (18 x 0.8 = 14.4) approximately 3.6 amino acid residues can be changed. What is a partial amino acid of 0.6 residues (18-14.4 = 3.6).

Claim 2 as to defining which 4 residues can be nonidentical.

Claim 5 is indefinite as to 100% overlap as SEQ ID NO: 1 and 2 are not identical.

Claim 6 is indefinite because there is no antecedent basis per se for "the modification" as claims 1 and 2 recite "modified versions". Claim 6 is also indefinite as to how or what the modification is that involves glycosylation. Is it addition of or removal of glycosylation.

Claim Rejections - 35 USC § 102

Claim1 is rejected under 35 U.S.C. 102(b) as being anticipated by Carson, (WO 94/14472). In disclosure on pages 27-30, Carson shows a sequence from Db 45-61 that is 51% identical to SEQ ID NO 1 of claim 1.

Based on claim interpretation that modified versions and isoforms are not required by claim 1 to be 80% identical, than can be any sequence such as that of Carson.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Alkhatib, (Virology 150,pp 479-490, 1986). In disclosure on page 484, Alkhatib shows a sequence from Db 584-599 that is 42% identical to SEQ ID NO 2 of claim 2.

Based on claim interpretation that modified versions and isoforms are not required to be identical to claim 1, than can be any sequence such as that of Alkhatib.

Conclusion

Claims 1-6 are rejected, and, no claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703)305-4243. The examiner can normally be reached on Monday-Friday from 6:30 am to 3:00 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923.The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

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Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER